

Serial No.: 10/536950

Attorney Docket No.: DFMP-P01-480

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A composition useful for the prophylaxis and/or treatment of an individual afflicted with a Hepatitis C virus (HCV) infection and/or at least one disease associated with a HCV infection, said composition comprising at least one agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D₃, all trans retinoic acid, salts of all trans retinoic acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl) benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl ~~naphthalenyl~~ naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN).
2. (original) The composition according to claim 1, wherein the composition comprises from 0.01 to 0.15 % by weight of the agent(s).
3. (currently amended) The composition according to claim ~~1 or~~ 2, wherein the composition comprises from 0.02 to 0.05 % by weight of the agent(s).
4. (currently amended) The composition according to ~~one of the preceding claims~~ claim 1, wherein the selenium salt is sodium selenite.

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5. (currently amended) The composition according to claim 1 one of the preceding claims, wherein the composition further comprises at least one of the following compounds[,]; pegylated α -, β -, and/or γ -interferon, non-pegylated (standard) α -, β -, and/or γ -interferon, and ribavirin.
6. (currently amended) The composition according to claim 1 one of the preceding claims, wherein the composition further comprises paraquat.
7. (currently amended) The composition according to claim 1 one of the preceding claims, further comprising at least one pharmaceutically acceptable carrier, excipient and/or diluent.
8. (currently amended) The composition according to claim 1 one of the preceding claims, wherein the individual afflicted with a HCV infection and/or at least one disease associated with HCV infection is a non-responder to interferon and/or ribavirin therapy.
9. (currently amended) A method for regulating the production of Hepatitis C virus in an individual and/or for preventing and/or treating Hepatitis C virus infection and/or diseases associated with HCV infection in an individual, the method comprising administering a pharmaceutical composition comprising a pharmaceutically effective amount of at least one agent selected from selenium, selenium salts, Vitamin D₃, all trans retinoic acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)-1-propenyl]benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl]carboxamido]benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN) to the individual Use of at least one

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~~of the agents selenium, selenium salts, Vitamin D₃, all trans retinoic acid, C₄–C₁₀ alkyl esters of all trans retinoic acid, salts of C₄–C₁₀ alkyl esters of all trans retinoic acid, C₄–C₁₀ alkyl amides of all trans retinoic acid, salts of C₄–C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C₄–C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₄–C₁₀ alkyl esters of 9-cis retinoic acid, C₄–C₁₀ alkyl amides of 9-cis retinoic acid, salts of C₄–C₁₀ alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl)]benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl]carboxamido]benzoic acid (AM-580), N-(4-hydroxyphenyl)retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN) for the preparation of a pharmaceutical composition for the treatment and/or prophylaxis of a Hepatitis C virus infection and/or a disease associated with HCV infection.~~

10. (currently amended) ~~Use~~ The method according to claim 9, wherein the pharmaceutical composition comprises from 0.01 to 0.15 % by weight of the agent(s).
11. (currently amended) ~~The method Use~~ according to claim 9 ~~or~~ 10, wherein the pharmaceutical composition comprises from 0.02 to 0.05 % by weight of the agent(s).
12. (currently amended) ~~The method Use~~ according to ~~one of claims 9 to 11~~ claim 9, wherein the selenium salt is sodium selenite.
13. (currently amended) ~~The method Use~~ according to ~~claim 9 one of claims 9 to 12~~ claim 9, wherein the pharmaceutical composition further comprises at least one of the following compounds[,]; pegylated α -, β -, and/or γ -interferon, non-pegylated (standard) α -, β -, and/or γ -interferon, and ribavirin.
14. (currently amended) ~~The method Use~~ according to ~~claim 9 one of claims 9 to 13~~ claim 9, wherein the pharmaceutical composition further comprises paraquat.

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15. (currently amended) ~~The method Use according to one of claims claim 9 to 14~~, wherein said pharmaceutical composition is for oral application.
16. (currently amended) ~~The method Use according to claim 9 one of claims 9 to 14~~, wherein said pharmaceutical composition is for topical application.
17. (currently amended) ~~The method Use according claim 15~~, wherein an oral dosage unit of said pharmaceutical composition contains from 1 to 300 mg, preferably 1 to 150 mg, more preferably from 1 to 100 mg, and particularly from 1 to 50 mg of the agent(s).
18. (currently amended) ~~The method Use according to claim 9 one of claims 9 to 17~~, wherein the ~~pharmaceutical composition is for the treatment and/or prophylaxis of an individual having a HCV infection and/or a disease associated with HCV infection, whereby the individual is a non-responder to interferon and/or ribavirin therapy.~~
19. (currently amended) ~~A The composition of claim 1, wherein said composition is in unit dosage form for oral administration, comprising as an active ingredient at least one agent selected from the group consisting of selenium, selenium salts, Vitamin D₃, all trans retinoic acid, C₁–C₁₀ alkyl esters of all trans retinoic acid, salts of C₁–C₁₀ alkyl esters of all trans retinoic acid, C₁–C₁₀ alkyl amides of all trans retinoic acid, salts of C₁–C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C₁–C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁–C₁₀ alkyl esters of 9-cis retinoic acid, C₁–C₁₀ alkyl amides of 9-cis retinoic acid, salts of C₁–C₁₀ alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl)] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl] carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR) and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene-carboxylic acid (AHPN), and further comprising a pharmaceutically acceptable carrier suitable for oral administration, said agent(s) being present in said unit dosage form in an amount of from about 1 to 50 mg wherein said unit dosage form is a tablet or capsule.~~

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20. (original) The composition of claim 19, further comprising paraquat.

21-22. (canceled)

23. (currently amended) A method for regulating the production of Hepatitis C virus in cells or cell cultures and/or for preventing and/or treating Hepatitis C virus infection and/or diseases associated with HCV infection in cells or cell cultures, the method comprising ~~the step of~~ administering a pharmaceutically effective amount of an agent selected from selenium, selenium salts, Vitamin D₃, ~~all trans~~ trans retinoic acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl)] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl ~~naphthalenyl~~ naphthalenyl] carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN) to the ~~individual cells or cell culture~~.

24-26. (canceled)

27. (currently amended) The method according to ~~one of claims 21 to 26~~ 23 or 55, further comprising administering paraquat.

28. (currently amended) The method of claim 9, wherein said composition is in a unit dosage form ~~Use of at least one of the agents selenium, selenium salts, Vitamin D₃, all trans retinoic acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, C₁ -~~

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~~C₁₀-alkyl amides of 9-cis-retinoic acid, salts of C₁–C₁₀-alkyl amides of 9-cis-retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl)] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)-carboxamide] benzoic acid (AM-580), N-(4-hydroxyphenyl)retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene-carboxylic acid (AHPN) for the preparation of a unit dosage form of a pharmaceutical composition for the treatment and/or prophylaxis of a hepatitis C virus infection and/or a disease associated with HCV infection, the pharmaceutical composition further comprising a pharmaceutically acceptable carrier.~~

29. (currently amended) ~~Use~~ The method according to claim 28, wherein the composition further comprises at least one of the compounds all trans retinoic acid, pegylated α -, β -, and/or γ -interferon, non-pegylated (standard) α -, β -, and/or γ -interferon, and ribavirin.
30. (currently amended) ~~The method Use~~ according to claim 28 ~~or 29~~, wherein the selenium salt is sodium selenite.
31. (currently amended) ~~The method Use~~ according to ~~one of claims 28 to 30~~ claim 28, wherein the composition further comprises paraquat.
32. (currently amended) ~~The method Use~~ according to claim 28 ~~one of claims 28 to 31~~, wherein said composition is for oral application.
33. (currently amended) ~~The method Use~~ according to claim 32, wherein the unit dosage form for oral application is a tablet or capsule.
34. (currently amended) ~~The method Use~~ according to claim 33, wherein the tablet or capsule comprises between 1 and 300 mg, preferably between 1 to 150 mg, more preferably between 1 to 100 mg, and particularly between 1 and 50 mg of the agent.
35. (currently amended) ~~The method~~ according to ~~one of claims 28 to 31~~ claim 28, wherein said composition is for topical application.

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36-41. (canceled)

42. (currently amended) A method for regulating the expression of the human cellular protein glutathione peroxidase-gastrointestinal in an individual comprising ~~the step of~~ administering to the individual a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D₃, all trans retinoic acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl naphthalenyl] carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent inhibits or activates at least partially the transcription of DNA and/or the translation of RNA encoding said human cellular protein glutathione peroxidase-gastrointestinal.

43. (original) The method according to claim 42, wherein the individual is a non-responder to interferon and/or ribavirin therapy.

44-45. (canceled)

46. (currently amended) A method for regulating the expression of the human cellular protein glutathione peroxidase-gastrointestinal in cells or cell culture comprising ~~the step of~~ administering to the cells or cell culture a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D₃, all trans retinoic acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C₁ - C₁₀ alkyl amide of 9-cis retinoic acid, salts

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of C₁ - C₁₀ alkyl amide of 9-cis retinoic acid, C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent activates at least partially the transcription of DNA and/or the translation of RNA encoding said human cellular protein glutathione peroxidase-gastrointestinal.

47. (currently amended) A method for regulating the activity of the human cellular protein glutathione peroxidase-gastrointestinal in an individual comprising ~~the step of~~ administering to the individual a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D₃, all trans retinoic acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C₁ - C₁₀ alkyl amide of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl amide of 9-cis retinoic acid, C₁ - C₁₀ alkyl amide of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl amide of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent interacts with said human cellular protein glutathione peroxidase-gastrointestinal.
48. (original) The method according to claim 47, wherein the individual is a non-responder to interferon and/or ribavirin therapy.
49. (currently amended) A method for regulating the activity of the human cellular protein glutathione peroxidase-gastrointestinal in cells or cell culture comprising ~~the step of~~ administering to the cells or cell culture a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D₃, all trans retinoic

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acid, C₁ - C₁₀ alkyl esters of all trans retinoic acid, salts of C₁ - C₁₀ alkyl esters of all trans retinoic acid, C₁ - C₁₀ alkyl amides of all trans retinoic acid, salts of C₁ - C₁₀ alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl esters of 9-cis retinoic acid, C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, salts of C₁ - C₁₀ alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl)] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl naphthalenyl] carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent interacts with said human cellular protein glutathione peroxidase-gastrointestinal.

50. (currently amended) The method according to any one of claims 36 to 49 42, 46, 47, and 49, further comprising administering paraquat.
51. (new) The composition according to claim 5, wherein the individual afflicted with a HCV infection and/or at least one disease associated with HCV infection is a non-responder to interferon and/or ribavirin therapy.
52. (new) The method according to claim 15, wherein the individual is a non-responder to interferon and/or ribavirin therapy.
- ~~52~~ 53. (new) The method according to claim 9, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal or which activates or stimulates at least partially the production of said human cellular protein glutathione peroxidase-gastrointestinal.
- ~~53~~ 54. (new) The method according to claim 13, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal or which activates or stimulates at least partially the production of said human cellular protein glutathione peroxidase-gastrointestinal.

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~~54~~ 55. (new) The method according to claim 18, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal or which activates or stimulates at least partially the production of said human cellular protein glutathione peroxidase-gastrointestinal.

~~55~~ 56. (new) The method according to claim 23, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal.